from Claim 1) within the scope of the restriction in claim 10 , i.e., the requirement that the method of the invention is used to treat pre-existing glomerulonephritis. Support for this change can be found, inter alia, in applicants' specification at page 23, lines 22-25.

**The §103 Rejections**

In the May 22 Office Action, the Examiner rejected applicant's pending claims 1-5 under 35 U.S.C. § 103 as allegedly being unpatentable over Wurzner et al. (Complement Inflamm., 1991; 1449, # 20) in view Couser et al. (J. Am. Soc. Nephrol., 1991; 1449, #5) and Sims et al. (U.S. Patent No. 5,135,916; 1449, #1).

Applicants have asserted that there is no teaching in the Wurzner et al. reference supporting the Examiner's contention that "it was apparent one of ordinary skill in the [art] would have had a reasonable expectation of success in producing the claimed invention." Applicants have also contended that the Couser et al and Sims et al references cited by the Examiner do not make up for the deficiencies in the Wurzner in this regard. The following is a more detailed consideration of these points.

Wurzner et al. disclose antibodies that, as discussed in applicants' specification, are useful in the process of the present invention. In discussing the useful properties of their antibodies, Wurzner et al. mention studies investigating the role of complement activity in animal

model systems, including animals models of kidney disease. Significantly, all of the animal model studies of kidney disease discussed by Wurzner et al. involved the inactivation of the complement system prior to the administration of agents responsible for the induction of kidney inflammation.

Wurzner et al. cited two animal model studies dealing with nephritis (the Falk and Jennette study, 1449 form reference 7, and the Groggel et al. study, 1449 form reference 10). The experimental animals used in each the studies had a genetic lesion in their complement system (an absence of C5 or C6, respectively) such that terminal complement activity was never present in these animals.

In making the pending rejection under 35 U.S.C. § 103, the examiner has also cited Couser et al., 1991 (1449 form reference 5). This reference reports the results of animal model experiments that were used to investigate certain aspects of the role of complement in glomerulonephritis. Significantly, in this study the experimental animals were de-complemented prior to the induction of kidney disease. In particular, the animals were experimentally depleted of complement in general, using cobra venom factor, or depleted of complement component C6 specifically, using an anti-C6 antibody preparation. In either case, the complement depletion procedure was initiated several hours before the animals were subjected to the experimental induction of immune complex nephritis.

Thus, the animal model glomerulonephritis experiments discussed by Wurzner et al. or cited by the Examiner only provide the knowledge that blockade of terminal complement activity can prevent the onset of kidney disease (i.e., can provide prophylaxis). They do not provide the information needed to form a reasonable prediction regarding the effects of complement blockade or depletion on animals where kidney inflammation has already been initiated, as was the case in the examples of applicants specification. In the studies reported in applicants examples, the induction of glomerulonephritis was initiated two weeks prior to the initiation of the administration of the anti-C5 antibodies providing complement inhibition (see, e.g., Example 1, page 35, lines 13-15).

Sims et al., U.S. Patent No. 5,135,916, also cited by the Examiner, does not provide any specific teaching of the use of anti-complement antibodies in the treatment of glomerulonephritis, and thus does not make up for the deficiencies in Wurzner et al., and Couser et al. with regard to the lack of a reasonable expectation of success in practicing the claimed invention.

In sum, applicants believe that their claims fully satisfy the requirements of section 103 of the Patent Statute. Applicants therefore respectfully request that the Examiner reconsider and withdraw his rejections under §103.



C

## II. Conclusion

In view of the foregoing, applicants respectfully submit that the above amendment puts their application in better condition for allowance or appeal, should an appeal be necessary, and respectfully request the entry of this amendment. Reconsideration and the issuance of a notice of allowance for this application are earnestly solicited.

Respectfully submitted,

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